

04526-6

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:

84526-6

Date of Issuance:

DEC 18 2013

Term of Issuance:

Conditional

Name of Pesticide Product:

Sanosil Halomist

NOTICE OF PESTICIDE:

- Registration
- Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Sanosil International, LLC
91 Lukens Drive, Suite A
New Castle, DE 19720

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The application referred to above, submitted under the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable under FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
 - a. The Silver DCI was issued on July 6, 2012 and you are responsible for addressing the data requirements outlined in the data call-in. A copy of the DCI can be located in the Docket for this active ingredient- <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0334-0032>. If you have specific questions about the DCI, contact Rose Kyprianou at 703-305-5354.
2. Submit a one-year study required to satisfy the storage stability and corrosion characteristics requirements (Guidelines 830.6317 and 830.6320). You have 18 months from the date of registration to provide these data.

A stamped copy of your labeling is enclosed for your records. Submit a final printed label before distributing or selling this product. The basic CSF dated 1/10/13 was found to be acceptable.

Signature of Approving Official:

Marshall Swindell
Product Manager Team 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)

Date:

DEC 18 2013

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Sanosil® HaloMist™

Disinfectant Fogging Solution

Effective against *Clostridium difficile* Spores

For Use in Healthcare Facilities with a minimum area of 1100 ft³ and maximum of 3700 ft³

| | |
|-------------------------------|---------|
| Active Ingredients: | |
| Hydrogen Peroxide..... | 5.00% |
| Silver..... | 0.01% |
| Other Ingredients..... 94.99% | |
| Total | 100.00% |

KEEP OUT OF REACH OF CHILDREN

CAUTION

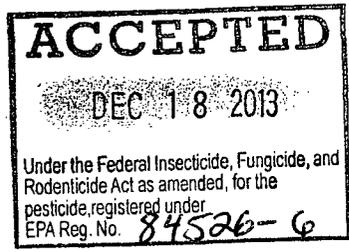
See [back] [side] [right] [left] panel for additional precautionary statements.

Net Contents: (as indicated on container)

EPA Reg. No. 84526-

EPA Est. No. (as indicated on container)

[See bottom or side for Lot/Data code]



Questions? Comments? [symbol of telephone]
Call: (1-800-726-6765)

[or] Visit us at (www.sanosilglobal.com)

[Made in USA]

Distributed by: Sanosil International LLC, 91 Lukens Drive, New Castle, Delaware 19720 [or an authorized Sanosil International distributor (insert name)]

Sanosil® is a licensed trademark of Sanosil Ltd. Switzerland

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with the label.

For use as a microbial disinfectant fogging solution in environments minimally 1100 ft³ up to 3700 ft³/104 m³ in size with a maximum height of 8 feet, for disinfection of dry, pre-cleaned, hard, non-porous, non-food contact surfaces in sealed spaces and rooms located in healthcare facilities and settings. Do not deviate from standard cleaning regimes when using Sanosil HaloMist. Use product only with Sanosil HaloFogger dispensing device following detailed instructions provided in the Sanosil HaloFogger User Manual. Read and follow directions in user manual on room preparation, room set up and treatment protocol, and equipment operating procedures for HaloFogger device.

Product effectively kills the following pathogens:
Bacteria:
 Clostridium difficile (spore form) (ATCC # 43598)
 Pseudomonas aeruginosa (Pseudomonas) (ATCC # 15442)
 Staphylococcus aureus (Staphylococcus) (Staph) (ATCC 6538)

New (this claim will only be used for the first six months after commercial introduction)

Miscellaneous Claims:

For use in Sanosil® HaloFogger
 For use in room fogging equipment [instrument[s] [device[s] [fogger[s] system[s]
 Healthcare-grade [Hospital-grade] disinfectant
 Ready-to-use [formula] [No mixing required]
 Go [Goes] above, beyond, under and around disinfecting sprays and wipes
 Advanced, Patented Formula
 No Wipe, No rinse, Dry Mist
 Whole [complete] Room Disinfection [Disinfecting] System
 Bleach [Chlorine] [Bleach and Chlorine] [Alcohol] free formula [technology] [disinfection] [disinfecting]
 [disinfectant]
 Easy, Effective
 Frequent use formula
 Great [suitable] for frequent use
 Leaves [room] surfaces disinfected
 Makes whole room disinfecting easier
 No [mixing] [or] [dilution] [diluting] [labor] required

General Performance Claims:

Effectively eliminates [pathogens] [bacteria] from hard, nonporous surfaces.
 Effective [alternative] broad-spectrum surface disinfectant
 Intended for use in all medical, healthcare, semi-critical care, and long term care environments.
 Gets everywhere, disinfects all pre-cleaned, hard, non porous room surfaces
 Reaches into every nook, crevice and corner that disinfecting sprays and wipes can't
 Reaches surfaces that regular disinfecting can't
 Reduce[s] the risk of cross contamination associated with using a rag, wipe or sponge
 Reduce[s] labor costs
 [Disinfectant] [Disinfects] [Daily] [Multi-action] [Multi-purpose] [Multi-room] [Multi-surface]
 [Disinfectant]
 Kills pathogenic bacteria
 Sanosil HaloMist meets EPA standards for healthcare [hospital] grade disinfectant
 Controls odors caused by [bacteria]
 Deodorizes by killing bacteria that causes odor[s]
 Deodorizing by killing odor-causing [bacteria] at their source
 Eliminates [removes] odors [caused by] [bacteria]
 Gets rid of odors by killing the [bacteria] [that cause them]

General Performance Claims (continued):

Helps prevent the build-up of odors by killing odor-causing bacteria [on hard, pre-cleaned, non-porous non- food contact surfaces]

Disinfects hard pre-cleaned, non-porous [non-food] contact surfaces in: [use sites]

For [hospital] [healthcare] [medical] [semi-critical care] [long term care] environments

For use in [hospital[s] [healthcare] [medical] [semi-critical care] [long term care] environments as a disinfectant

For use on hard, pre-cleaned, non-porous surfaces located in: [use sites]

Great [suitable] for whole [complete] room [disinfecting] [disinfection]

Treats, does not cover up [no residue] [no need to rinse after use] as a disinfectant

Use on hard to reach areas [like nooks and crannies]

Use this product in [use sites]

Kills [eliminates] 99.9999% of [Clostridium difficile] [C-diff] spores

Kills [eliminates] 99.99% of Pseudomonas aeruginosa [Pseudomonas] bacteria

Kills [eliminates] 99.99% of Staphylococcus aureus [Staphylococcus] [Staph] bacteria

Multiple [Multi-faceted] killing mechanism[s]

Multiple [Multi-faceted] mechanisms of killing action

Multiple modes of killing action

Specific Disinfecting Claims

Kills [eliminates] bacteria [Clostridium difficile] [C-diff] spores

Kills [eliminates] 99.9999% of [Clostridium difficile] [C-diff] spores

Kills [eliminates] Pseudomonas aeruginosa [Pseudomonas] bacteria

Kills [eliminates] 99.99% Pseudomonas aeruginosa [Pseudomonas] bacteria

Kills [eliminates] Staphylococcus aureus [Staphylococcus] [Staph] bacteria

Kills [eliminates] 99.99% of Staphylococcus aureus [Staphylococcus] [Staph] bacteria

First disinfectant [disinfecting] fogging [solution] [formula] [product] proven to kill [eliminate] bacteria [Clostridium difficile] [C-diff] spores

EPA registered disinfectant [disinfecting] fogging [solution] [formula] [product] for whole [complete] room surface disinfection [disinfecting]

An effective disinfectant [solution] [formula] [product] for use in healthcare facilities

An effective disinfectant [solution] [formula] [product] for use in healthcare facilities for whole [complete] room surface disinfection [disinfecting]

An effective disinfectant [solution] [formula] [product] for use in [hospital[s] [healthcare] [medical] [semi-critical care] [long term care] environments

An effective disinfectant [solution] [formula] [product] for use in [hospital[s] [healthcare] [medical] [semi-critical care] [long term care] environments for whole [complete] room surface disinfection [disinfecting]

Effective against bacteria

Specific Disinfecting Claims (continued):

Kills [eliminates] [destroys] [bacteria] on hard, non-porous surfaces
 Kills [eliminates] bacteria [odors] and deodorizes
 On hard, pre-cleaned, non-porous, non-food contact surfaces this product kills [eliminates] bacteria
 Surface Disinfectant
 Whole [Complete] Room Surface Disinfectant
 This product reduces the risk of cross contamination of bacteria on hard, pre-cleaned, non-porous surfaces
 This product [helps] aids] in the reduction of cross contamination of bacteria on hard, pre-cleaned, non-porous surfaces
 This product helps fight the spread of bacteria on hard, pre-cleaned, non-porous surfaces
 [You can] [Use] this product in places that are difficult to [disinfect] [sanitize] [reach] such as nooks and crannies

Healthcare Use Sites:

This product [or product name] is designed specifically as a healthcare-grade [ready-to-use] disinfectant [disinfecting] fogging [solution] [formula] [product] for use in the following settings of 1100 ft³ up to 3700 ft³:

Ambulatory Surgical Centers (ASC)
 Anesthesia Rooms or Areas
 [Assisted Living or Full Care] Nursing Homes
 CAT Laboratories
 Central Service Areas
 Central Supply Rooms or Areas
 Critical Care Units or CCUs
 Dental operatories
 Dentist office
 Examination room[s]
 Dialysis Clinics [Facilities]
 Donation Centers [blood] [plasma] [semen] [milk] [apheresis]
 Emergency Rooms or ERs
 Eye Surgical Centers
 Health Care Settings or Facilities
 [Hospital] Kitchens (non-food contact surfaces)
 Hospices
 Intensive Care Units ICU[s] [areas]
 Isolation Areas
 Laundry Rooms
 Laboratories
 Long Term Care Facilities
 Medical Facilities
 Newborn or Neonatal [Nurseries] [Intensive Care] Units [NICU]
 Nursing or Nursing Stations
 Operating Rooms or ORs
 Ophthalmic Offices
 Orthopedics

Healthcare Use Sites (continued):

Out Patient [Surgical Centers (OPSC)] [Clinics] [Facilities]

Patient Areas

Patient Restrooms

[Pediatric] Examination Rooms or Areas

Pediatric Intensive Care Units [PICU]

Pharmacies

Physical Therapy Rooms or Areas

Psychiatric Facilities

Public [Care] Areas

Radiology or X Ray Rooms or Areas

Recovery Rooms

Rehabilitation Centers

Respiratory Therapy Rooms or Areas

Restrooms

Surgery Rooms or Operating Rooms or ORs

Waiting Rooms or Areas

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID **If in Eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for treatment advice. **If on Skin:** Rinse skin immediately with plenty of water for 15-20 minutes. The affected skin can turn white and itchy. These symptoms will disappear within a few minutes.

Questions? Comments, or in case of an emergency, call toll free (1-877-SANOSIL or 1-877-726-6745). Have the product container or label with you when calling a Poison Control Center, or doctor, or going for treatment.

STORAGE AND DISPOSAL Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Keep out of direct sunlight and away from heat. Do not freeze. Store in original container in areas inaccessible to small children and pets.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

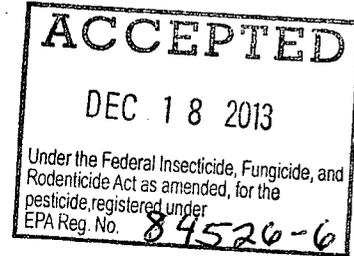
Container Disposal: Non-refillable container. Do not reuse or refill this container. Recycle, if available, or discard in trash. If product leaking or spills should occur, please dilute with water and dry with absorbent material, or dilute with water as it is flushed into waste water drain.

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Sanosil Halo Fogger User Manual

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1. General Information

1.1 Sanosil HALOMIST

Sanosil HALOMIST has been registered by Sanosil International in accordance with Federal Regulations for the specific uses described in this package insert. Uses other than as specified and described are not permitted and may not be effective in the disinfection of exposed surfaces in pre-cleaned, sealed rooms.

2. Sanosil HALOMIST Disinfectant Application Process

Only Sanosil HALOMIST should be used in the Sanosil Halo Fogger. Effective application of Sanosil HALOMIST requires adequate product concentration and exposure time. The Sanosil Halo Fogger is designed to achieve the correct concentration and contact time of Sanosil HALOMIST within a defined area.

Read the Sanosil Halo Fogger User's Manual prior to initiating the application process to determine the appropriate steps to take in development and application of the process.

Sanosil HALOMIST is applied at a rate of approximately 1.0 oz per minute for a minimum of 10 minutes and maximum of 60 minutes depending upon the room size. For use in rooms 1100 ft³ up to 3700 ft³. Do not use in rooms smaller than 1100 ft³.

The Sanosil Halo Fogger uses air as a carrier to deliver a dry mist (suspension of small liquid droplets in the air) of Sanosil HALOMIST to exposed surfaces inside a sealed room for a selected time based on the size of the room. Read the Sanosil HALOMIST MSDS prior to fogging. The Sanosil HALOMIST disinfectant is continuously fogged for the required dispensing time to maintain the desired concentration of the product mist. The Sanosil Halo Fogger will automatically stop fogging at the selected time. Sanosil HALOMIST decomposes into water and oxygen.

The Sanosil HALOMIST process can consist of 1, 2 or 3 phases depending upon application:

1. Dehumidification - The Dehumidification phase is required only if the room to be disinfected is above 50% relative humidity. In rooms with higher humidity levels the dispensing of product can be affected by increased condensation levels, which can decrease the efficacy of the product. Room air is first circulated in the sealed treatment room by the dehumidifier to reduce humidity to a predetermined level in the 30-50% relative humidity (RH) range. This permits the target Dry Mist Hydrogen Peroxide (DMHP) concentration to be maintained below condensation levels during the disinfection phase. The time to reach the targeted dehumidification level increases with the volume of the room, and is dependent on environmental conditions.

2. Disinfection - For all disinfecting applications, Sanosil HALOMIST is continuously fogged for a selected time to obtain the target DMHP concentration over a pre-established period of time for the volume of the enclosed area. It is recommended the room temperature be in the range of 20° C +/- 2° C (68° F +/- 4° F). Whenever possible, delay room re-entry and allow treated room to remain unoccupied overnight for safety and maximum efficacy.

3. Post Dehumidification - When accelerated room re-entry is necessary, the dehumidifier will speed the reduction of the DMHP concentration within the room to a 1 ppm level prior to reentry into the room by trained applicators. Treated rooms may not be released for general public use until one hour after a 1 ppm level of DMHP is achieved in the room as indicated by appropriate instrumentation.

3. User Safety Requirements

1. Hazards to Humans and Domestic Animals. CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco
2. Users should remove clothing and PPE immediately if Sanosil HALOMIST gets inside. Then wash thoroughly and put on clean clothing.
3. PPE (Personal Protective Equipment) is required for special room re-entry procedures. See Section 5.6.

4. Disinfection Management Plan

4.1 GENERAL - Employees of the site to be disinfected should develop a site specific Disinfection Management Plan (DMP) for each room to be fogged with Sanosil HALOMIST. The user is responsible for all tasks of the disinfection process unless noted in the DMP and must be on site for the entire disinfection treatment process. The DMP must address a full characterization of the site, and include appropriate monitoring and notification requirements, consistent with, but not limited to, the following:

1. Inspect the structure and or area to determine its suitability for disinfection (size, non-porous surfaces, pre-cleaned). Size of room/area must be between 1100 ft³ and 3700 ft³.
2. Seal the room to be treated adequately to ensure that DMHP levels outside the room are kept at acceptable levels and that there is adequate coverage of product within the room. Monitor any occupied adjacent rooms and/or buildings to ensure safety.
3. Prior to each disinfection, review any existing DMP, MSDS, Equipment Manuals and other relevant safety procedures with company officials and appropriate employees.
4. Consult with company officials in the development of procedures and appropriate safety measures for nearby workers who will be in and around the area during application and aeration.
5. Consult with company officials to develop an appropriate monitoring plan that will confirm that nearby workers and bystanders are not exposed to levels above the allowed limits during application. This plan must also demonstrate that nearby residents will not be exposed to concentrations above the allowable limits.
6. Confirm the placement of placards to secure entrance into any area under disinfection.
7. Confirm the required safety equipment is in place and the necessary manpower is available to complete disinfection.

These factors must be considered in putting a DMP together. It is important to note that some plans will be more comprehensive than others. All plans should reflect the experience and expertise of the applicator and circumstances at and around the structure and/or area. In addition to the plan, the user must read the entire label and equipment manuals and follow all directions carefully. If the user has any questions about the development of a DMP, contact Sanosil International or authorized distributor for further assistance.

4.2. PERSONNEL

1. Training and Certification of Applicators

Prior to use, applicators must be adequately trained and certified by Sanosil International or its authorized distributor or reseller on the hazards and label directions for Sanosil HALOMIST,

on the use and operation of the DMHP application equipment, Sanosil HALOMIST monitoring procedures and when appropriate, validation procedures.

2. Confirm in writing that all personnel in and around the area to be fogged have been notified prior to application of the disinfectant. Consider using a checklist that each employee initials indicating that they have been notified.
3. Instruct all disinfection personnel about the hazards that may be encountered; and about the selection of PPE, including detection equipment.
4. Confirm that all personnel are aware of and know how to proceed in case of an emergency situation.
5. Instruct all personnel on how to report any accident or incidents related to disinfectant exposure.
6. Establish a meeting area for all personnel in case of emergency.
7. Confirm that all applicators have been trained in the use of Sanosil HALOMIST and are in good standing including the required refresher training.
8. Develop a Worker Health and Safety Plan as required by OSHA for applicators. The owner and operators of the facility being treated should have a Worker Health and Safety Plan as required by OSHA developed for their employees located within close proximity of the application process.

4.3. MONITORING

A. Perimeter safety

1. Monitoring of Sanosil HALOMIST concentrations must be conducted immediately adjacent to the fogged space to prevent excessive exposure and to determine where exposure may occur. Document where monitoring will occur.
2. Keep a log or manual of monitoring records for each disinfection site. This log must at a minimum contain the timing, number of readings taken and level of concentrations found in each location.
3. When monitoring for leaks, document that there is no DMHP present above the 1.0 ppm level. Subsequent leak monitoring is not routinely required. However spot checks must be made, especially if conditions significantly change.
4. Monitoring must be conducted during aeration and corrective action taken if H₂O₂ levels exceed the allowed levels in an area where bystanders or nearby residents may be exposed.

Ensure that the adjacent areas where levels have exceeded 1 ppm are evacuated by general personnel and that proper respiratory protection is utilized by applicators that enter the area. Continue monitoring the area until levels are below 1 ppm DMHP. The treated room and adjacent areas must remain unoccupied until one hour after DMHP levels are at or below 1ppm.

B. Efficacy

1. Proper placement of Chemical Indicators (CIs) in all areas of the room to assure consistent delivery.
2. Document Sanosil Halo Fogger run times, temperature, room humidity and CI color change.

4.4. SEALING PROCEDURES

1. Sealing must be adequate to prevent any leaks. Care should be taken to ensure that sealing materials remain intact until the disinfection is complete. Verify effectiveness of the sealing process by conducting a smoke stick test to ensure there are no leaks where openings have been sealed in the room.
2. If the structure and/or area has been fogged before, review the previous DMP information.
3. Make sure that construction or remodeling has not changed the building in a manner that will affect the disinfection process.

4. Warning placards must be placed on every possible entrance to the disinfection site.

4.5. APPLICATION PROCEDURES AND DISINFECTION PERIOD

1. Plan carefully and apply disinfectant in accordance with the label requirements.
2. When entering into the area under disinfection always work with two or more people under the direct supervision of a trained applicator wearing appropriate PPE.
3. Provide watchmen when a disinfection site cannot otherwise be made secure from entry by unauthorized persons.
4. Follow Sanosil Halo Fogger Use Instructions (See Section 5.)

4.6. POST-APPLICATION OPERATIONS

1. Provide watchmen when you cannot secure the disinfection site from entry by unauthorized persons during the aeration process.
2. Ventilate and aerate in accordance with structural limitations. If possible, It is recommended that treated air be vented outside of building.
3. Turn on ventilating or aerating fans where appropriate.
4. Use a suitable DMHP detector before reentry to determine disinfectant concentration. (example: Drager PAC III or ATS PortaSens II)
5. Keep written records of monitoring to document completion of aeration.
6. Remove warning placards when aeration is complete.
7. Inform business clients that employees or other persons may return to work or otherwise be allowed to re-enter the aerated structure after a minimum of one hour once the room concentration reaches 1 ppm.

4.7. CRITERIA FOR SUCCESSFUL DISINFECTION:

1. All CIs that are properly recovered and evaluated exhibit a visible color change following exposure to DMHP.

5. Sanosil Halo Fogger Use Instructions

5.1 Room Preparation

CAUTION – Before proceeding, ensure that personnel who operate the Sanosil Halo Fogger have received appropriate training, including:

- Review Sanosil Halo Fogger User Manual and Sanosil HALOMIST Labeling
- Review Sanosil HALOMIST Material Safety Data Sheet

1. Remove porous curtains, fabric and associated porous items from room, including: bed linens, waste products and visible dirt.
2. Cleaning: All hard, non-porous surfaces with visible or non-visible soils must be clean. Wash soiled surfaces with a generic cleaning agent (i.e. soap and water, a multi-purpose cleaner, etc.) using a cloth, sponge, wipe or appropriate cleaning device to ensure visible soils are removed. All the surfaces within the treatment area must be completely dry to the touch prior to initiating DMHP application.

IMPORTANT – The Sanosil Halo Fogger does not replace the requirement for manual room cleaning. You must follow facility's cleaning procedure before using the Sanosil Halo Fogger.

5.2. Room Set Up:

1. It is recommended that all ventilation systems, including HVAC, be turned off for the duration of the fogging process.
2. Seal the room to be treated to ensure that DMHP levels outside the room are kept at acceptable levels and that there is adequate coverage of product within the room. Seal any supply or return vents and duct work to prevent distribution of Sanosil HALOMIST through the ductwork. Cover any smoke detectors. Sealing techniques can vary, but most often includes polyethylene sheeting and adhesive tape. Verify effectiveness of the sealing process by conducting an air draft potential analysis using a smoke stick test to ensure there are no leaks where openings have been sealed in the room.
3. Open internal doors, cupboards, and drawers of room furniture unless specifically directed to leave them closed (as in the operating room).
4. Remove mattresses from beds. Mattresses with non-porous covers can be tilted up against side of bed. Mattresses not protected with a non-porous cover must be removed from room during treatment procedure.
5. Monitor areas immediately adjacent to the fogged space to ensure levels are below TWA for DMHP.
6. If possible, modify ambient conditions in the room to meet the following recommended parameters: Temperature: 20° C +/- 2° C (68° F +/- 4° F); Relative Humidity: between 30% - 50%.
7. Assure all personnel have vacated the treatment room prior to DMHP application. Remove all plants, animals, beverages and food.
8. Close all windows and seal door(s) from outside of room being treated.
9. Applicators must not re-enter the treated room until exposure levels of DMHP are at or below one ppm. Do not release the treated room to the general public until 1 hour after a level of one ppm DMHP is achieved in the room.
10. Placarding of Treatment Room: The applicator must placard or post all entrances to the designated buffer zones with signs in English bearing:
 1. The signal word "CAUTION/PRECAUTION" in red.
 2. "Area under treatment, "DO NOT ENTER/NO ENTRY."
 3. The statement "This sign may only be removed after the treatment of enclosed area, one hour after DMHP levels are less than or equal to one ppm".
 4. Identification of Sanosil HALOMIST disinfectant as a hazard associated with the treatment process
 5. Contact information for the applicator.

All entrances to the treatment room must be placarded. Placards must be placed in advance of the treatment in order to keep unauthorized persons from entering the treated room. Placards can be removed one hour after the treatment room contains concentrations of DMHP are at or below 1 ppm and the ventilation process has been completed.

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5.3 Treatment Procedure Protocol

1. Position the Sanosil Halo Fogger in a corner of the room approximately one foot away from the wall, pointing the nozzle towards the center of the room. Choose a corner farthest away from vents, ductwork and door. **IMPORTANT** - Dispensing airflow path from the Sanosil Halo Fogger must remain unobstructed during entire treatment procedure.
2. Measure the length, width and height of the room. Round up to the nearest cubic foot or cubic meter. These measurements will determine the final room size and recommended run-time of the Sanosil Halo Fogger.
3. Plug the Sanosil Halo Fogger into a standard, grounded electrical wall outlet. When the power connection has been made, the green status indicator light on top of the device will illuminate.
4. Using the chart below (also found on the rear of the device or in the Sanosil Halo Fogger User Manual) determine the Fogging Time based on the room size (cu ft or m³) from Step 2 above.

Fogging Time

| ft ³ | - Room Size - | m ³ | Fogging Time | Minimum Wait Time Before Checking H ₂ O ₂ Level | Room Re-Entry by Applicators +60 Minutes |
|-----------------|---------------|----------------|--------------|---|--|
| 1,110 - 1,800 | | 11 - 50 | 10 minutes | 110 minutes | Treated room can |
| 1,800 - 2,600 | | 50 - 75 | 15 | 120 | be reoccupied |
| 2,600 - 3,660 | | 75 - 104 | 25 | 140 | one hour after |
| | | | | | hydrogen peroxide concentration level |
| | | | | | is determined to |
| | | | | | be at or below one ppm and ventilation has been completed. |

5. Turn the timer dial on the top of the Sanosil Halo Fogger to the number of minutes specified for your room size. **Do not set the timer for longer than the suggested time. Excessive fogging can cause condensation, which may reduce effectiveness and may activate fire alarm systems.**
6. Check the fluid level indicator lights to see level of Sanosil HALOMIST in the Sanosil Halo Fogger. It is recommended the unit reservoir be topped off before proceeding with the treatment process. Refer to the Setup and Filling, Section 8.1.
7. Press and hold the Sanosil Halo Fogger Start button for 2 seconds. The green status indicator light will begin to flash red, indicating that you have 30 seconds to leave the room before the

Sanosil Halo Fogger device begins to operate.

8. Close the door to the room after you have exited. Post a sign on the door indicating that the room should not be entered during treatment process. Note time treatment process was started on room sign.
9. After 30 seconds, the status indicator light will turn solid red and the Sanosil Halo Fogger will begin to dispense Sanosil HALOMIST into the room. It is likely that you will hear the Sanosil Halo Fogger running through the door.
10. When the Sanosil Halo Fogger has finished dispensing the room will be full of atomized Sanosil HaloMist disinfectant. The status indicator will remain illuminated red. DO NOT ENTER ROOM at this time.
11. The treated room must remain unoccupied until the minimum room re-entry wait time has expired and hydrogen peroxide concentration level (ppm) has been checked. 110 minutes is the minimum wait time for re-entry; length of wait time increases with room size. (*See chart, step 4 above.*) Whenever possible, delay re-entry and allow treated room to remain unoccupied overnight for safety and maximum efficacy. Hydrogen peroxide concentration levels must be at or below one ppm for safe room re-entry. Once safe levels are determined to be at or below one ppm, it is recommended that venting to the outside be started to allow increased ventilation and airflow circulation in the room. Uncover smoke detectors.

Upon expiration of room re-entry wait time, to assure occupational health levels are not exceeded, using a handheld hydrogen peroxide detector (example: Drager PAC III or ATS PortaSens II), applicator in appropriate PPE verifies safe hydrogen peroxide concentration level is at or below one ppm. If level is not at or below one ppm, wait an additional 10-minutes and re-check. Continue to check until safe health exposure level is at or below one ppm. Treated room can be re-occupied one hour after hydrogen peroxide concentration level is determined to be at or below 1 ppm.

12. When treatment is complete, unplug the Sanosil Halo Fogger from the power source.
13. Store Sanosil Halo Fogger upright, in a safe, dry location. It is not necessary to drain Sanosil Halo Fogger of disinfectant.

Disinfecting for High Humidity Environments and Applications Requiring Accelerated Room Re-Entry – Special Instructions

- A. Prepare the room as outlined in Sections 5.1, Room Preparation and 5.2 Room Set Up – then,
 1. Room humidity level of 30% – 50% or less is recommended before starting the treatment process. *Some rooms may have a higher humidity level which can extend the room re-entry time.* Position the dehumidifier next to Sanosil Halo Fogger. Verify that the dehumidifier's reservoir is empty or empty reservoir prior to use.
 2. Plug dehumidifier into the correct location on the Sanosil Power Module, and then plug the power module into a standard, grounded electrical wall outlet.
 3. Turn on dehumidifier; set fan to highest speed setting. Check humidity level with humidity sensor; if humidity level is above 50%, let dehumidifier run until

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the humidity level is reduced to recommended level.

4. Plug the Sanosil Halo Fogger into the correct location on the Sanosil Power Module. When the power connection has been made, the green status indicator light on top of the device will illuminate.

5. Continue following steps section 5.3 – Treatment Procedure Protocol

5.4. Special Room Re-Entry Instructions:

WARNING – During the treatment process, Sanosil HALOMIST mist (liquid aerosol) is dispensed. Personal protection equipment including the use of an appropriate air respirator is required for hydrogen peroxide concentration levels exceeding safe re-entry levels (ppm).

5.4.1 Early Room Re-Entry

In case of an emergency and/or unknown levels of Hydrogen peroxide mist that may exceed applicable exposure limits within the treated room requires use of a Self Contained Breathing Apparatus (SCBA) or an airline respirator. When entering into an area with the Sanosil Halo Fogger running, always work with two or more people under the direct supervision of a trained applicator, with all people wearing appropriate PPE.

5.4.2 Re-Entry to Sealed Room by Applicator

Re-entry to a sealed room by a trained applicator is allowed under the following circumstances:

- a. Only enter the room to perform a planned task, e.g. to retrieve equipment, open windows, augment aeration process etc; and leave the room in the shortest time possible.
- b. Always wear wrap around style goggles to protect against irritation of eyes.
- c. Determine Hydrogen peroxide levels prior to room entry using a handheld hydrogen peroxide detector (example: Drager PAC III or ATS PortaSens II).
- d. Hydrogen Peroxide levels between 1 and 10 ppm requires at least half-face piece respirator (and appropriate eye protection) with either 3M 6003 or 6006 (organic vapor/acid gas or multi-gas) cartridge in combination with particulate filter (i.e. 5N11 or 5P71).*
- e. Using a full-face piece respirator (when quantitatively fit tested) with either cartridge mentioned in 5.4.2.c gives an Assigned Protection factor of 50 for use up to 50ppm of Hydrogen Peroxide.*

*3M Technical Bulletin #185 and Solvay Chemicals Technical Communication TDS No. HOOH-PAA-RESP

Otherwise, do not re-enter the treated room until one hour after exposure levels are at or below one ppm and the ventilation process has been completed.

5.5. Releasing Treated Sealed Room for Return to Service and the General Public

1. The treated room can be released for general public use one hour after DMHP levels are determined to be at or below one ppm and the ventilation process has been completed. If possible, it is recommended that treated air be vented to the outside of the building.
2. Once DMHP levels are determined to be at or below one ppm, applicators may re-enter the treated room and remove any sealing materials including any covered fire alarms and disconnect or remove the Sanosil Halo Fogger from the treated sealed room.
3. Turn on ventilation systems to the outside if available.
4. Remove placards and release the treated room for normal operation and use one hour after the levels of DMHP are determined to be at or below one ppm.

6. Precautions

6.1 Caution Statements

A caution statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately, could lead to serious injury or death.

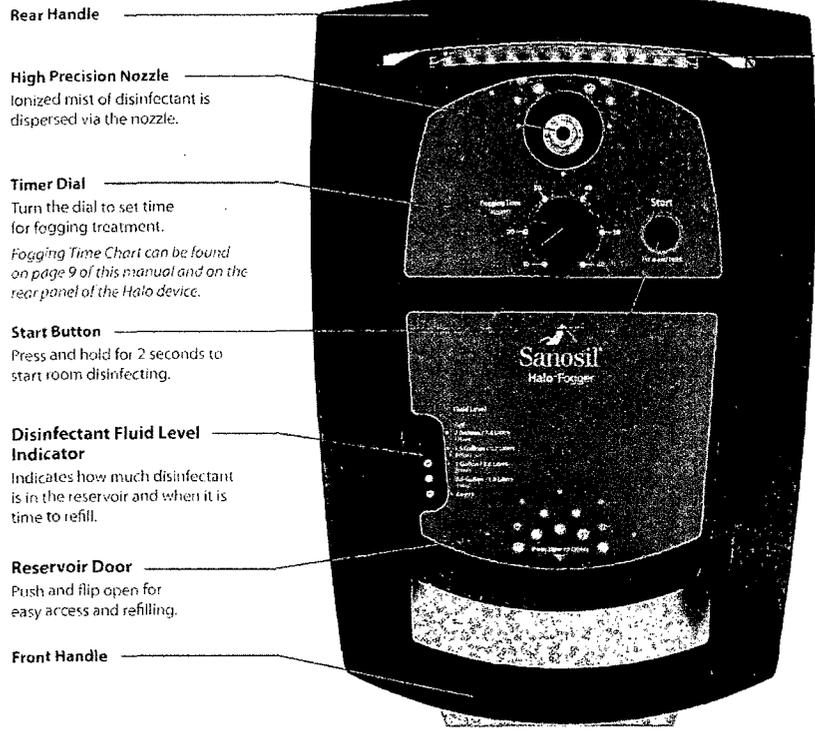
1. **KEEP OUT OF REACH OF CHILDREN.**
2. Carefully read all instructions, warnings, cautions and first aid statements prior to use.
3. Do not enter room while the Sanosil Halo Fogger is in use. Keep door and windows closed.
4. Use only as directed.
5. Allow Room Re-entry Wait Time to expire before re-occupying the room. Re-entry before wait time has expired could result in sensory irritation and should only be done while using proper personal protection equipment (PPE) including, at a minimum, wrap-around style goggles, N-95 respirator mask and gloves.
6. Avoid inhalation of vapors or skin and eye contact with Sanosil HALOMIST fog.
7. The Sanosil Halo Fogger is designed for ease-of-use. However, only properly trained individuals should use this device.
8. Electric shock hazard. Do not plug in if electrical plug or parts are wet.
9. There are no user-serviceable parts inside the Sanosil Halo Fogger other than the nozzle. An operator may only perform maintenance procedures specifically described in this manual. The manufacturer should make all other repairs.
10. While in use, the body of the Sanosil Halo Fogger may become warm to the touch. Use caution when handling.
11. Use personal protection equipment (PPE) including wrap-around style goggles and gloves when pouring disinfectant fluid into the device. Avoid splashing or overfilling which could harm the user and/or the device.
12. Specific warning and caution statements are included for Sanosil HALOMIST (see Section 6.3).
13. Sanosil International is not responsible for any injury or damage caused by using this device outside of the specific parameters detailed in this manual.

6.2 Operation Warnings

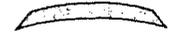
These warnings pertain to the actual use of the Sanosil Halo Fogger unit.

1. To ensure effectiveness and safety, use **only** with Sanosil HALOMIST. Using any other manufacturer's disinfecting or cleaning product **will** result in serious injury, exposure and environmental damage.
2. Position the device on a secure surface to prevent rolling or moving while in use.
3. Use only a Sanosil supplied electrical cord.
4. Always unplug the power cord from the outlet before moving the device.
5. Clean debris from the device nozzle and funnel on a regular basis according to the instructions in this manual (see Section 9, Maintenance).
6. Regularly check disinfectant fluid level to ensure sufficient volume is present to treat each particular room size.
7. Do not set the timer for longer than the suggested fogging time. Excessive fogging can create condensation, which may activate fire alarm systems.
8. Protect this device from severe impact or shock.
9. Take care to prevent water or other fluid from entering the device. Should this occur, allow to completely dry before use. Check the accuracy of all operating functions.
10. Do not tip the Sanosil Halo Fogger on its side at any time unless completely empty and dry.
11. Store Sanosil Halo Fogger in an upright position, in a safe, dry location. Do not place anything on top of the device.
12. Additional warning and caution statements are included for Sanosil HALOMIST.

7. Walk Around of Sanosil Halo Fogger



Status Indicator Light
Displays the current status of the Halo device.



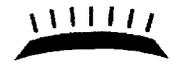
Green: Indicates one of the following:

- Plugged in and ready for use
- Treatment process is complete

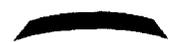


Flashing Green: Indicates one of the following:

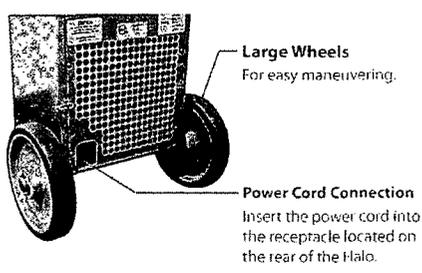
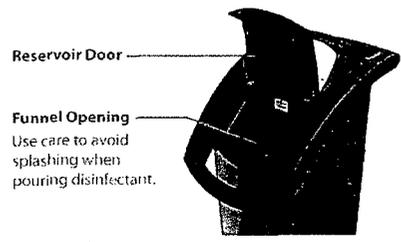
- Reservoir Door is not closed correctly
- An error has occurred. (Refer to Troubleshooting section of this manual, page 11.)



Flashing Red: Indicates 30 second countdown after the Start button has been pushed



Red: Indicates the device is on and dispensing disinfectant. The room should be unoccupied.



8. Getting Started with the Sanosil Halo Fogger (HALO)

8.1 Setup and Filling

THE SANOSIL HALO FOGGER IS DESIGNED FOR USE WITH SANOSIL HALOMIST AND SHOULD NOT BE OPERATED WITH ANY OTHER MANUFACTURER'S DISINFECTING OR CLEANING PRODUCT.

Setup Instructions

Locate the connector end of the power cord. Insert the connector into the power receptacle

located at the bottom of the rear panel of the Sanosil Halo Fogger. Ensure that the connector is securely in place. Plug the Sanosil Halo Fogger into a standard electrical outlet. The green status indicator light will illuminate.

Filling Instructions

1. Push down on the Sanosil Halo Fogger Reservoir Door in the area labeled "Push Here to Open." Lift to open.
2. Locate the disinfectant fluid level indicator lights to the left of the funnel. One orange light will be illuminated indicating the Sanosil Halo Fogger is empty.
3. Use personal protection equipment (PPE) including wrap-around style goggles and gloves when pouring disinfectant fluid into the device.
4. Open a gallon (3.8 liters) bottle of Sanosil HALOMIST and **SLOWLY** pour the contents into the funnel area. **AVOID SPLASHING.**
5. The fluid level indicator lights will illuminate as you pour to show how much disinfectant is in the device.
6. The Sanosil Halo Fogger holds two gallons (7.6 liters) of disinfectant when full. Stop pouring when the top green light on the fluid level indicator is illuminated. Do not overfill.
7. Wipe up any spills with a clean paper towel or rag. Thoroughly rinse off gloves and hands.
8. Close Reservoir Door, ensuring it "clicks."
9. The Sanosil Halo Fogger is now ready to be used.

9. Maintenance

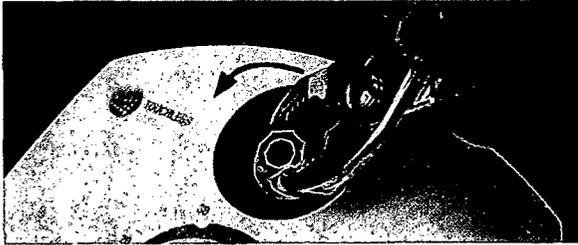
9.1 Nozzle Cleaning and Alignment

Before performing any maintenance to the Halo, disconnect the power cord from the electrical outlet.

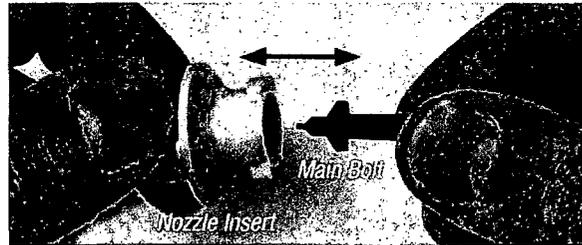
Nozzle Cleaning and Alignment

To avoid build up of deposits in the nozzle, it is recommended that you clean the nozzle on the Halo on a regular basis. Correct alignment of the nozzle is critical for optimal performance.

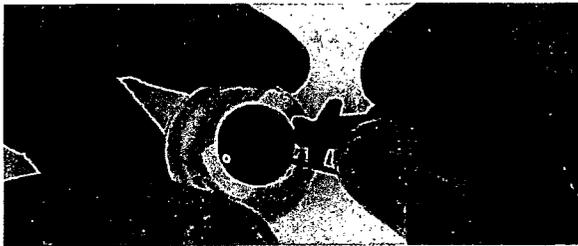
Step 1. **Unplug Halo from power source.**



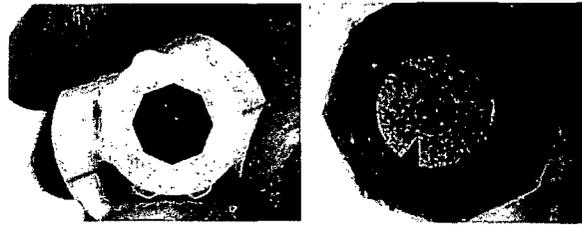
Step 2. **Remove Nozzle.** Using adjustable pliers, carefully turn nozzle counter-clockwise 90° and remove.



Step 3. **Separate Parts.** Remove Main Bolt from Nozzle Insert. Soak both parts in a conventional household de-liming agent for two hours. Rinse parts thoroughly with water.



Step 4. **Reassemble Nozzle.** Carefully insert the Main Bolt back into the Nozzle Insert. Make sure the "wings" on the Main Bolt nest into the slots down inside the Nozzle Insert.



IMPORTANT - Position Main Bolt so a uniform gap surrounds the nozzle tip.



Step 5. Carefully **reinstall the nozzle into the Halo**, turning nozzle clockwise 90° to lock into place. Test Halo for straightness of nozzle stream.

Funnel Cleaning

The fluid funnel inside the Halo device should be checked for debris on a regular basis. Visually inspect the funnel. If any debris is present, wipe with a clean towel dampened with water.

Ensure that the funnel screen is in place.

9.2 Funnel Cleaning

The fluid funnel inside the Sanosil Halo Fogger should be checked for debris on a regular basis. Visually inspect the funnel. If any debris is present, wipe with a clean towel dampened with water. Ensure that the funnel screen is in place.

10. Troubleshooting

The following table of potential indicators provides a quick reference of the descriptions, probable causes and most common solutions regarding the operation of the Sanosil Halo Fogger. If the information in this table does not describe or solve the problem you are having, contact Sanosil Customer Service at 1 877 726 6745, Monday through Friday, 9:00AM to 5:00PM EST. For International calls dial +1 302 454 8102.

| Symptom | Possible Cause | Solution |
|--|---|--|
| No mist is being produced | The nozzle is clogged or misaligned. | Remove the nozzle and clean according to the instructions in this manual. |
| | The disinfectant fluid tank is empty. | Check the fluid level indicator lights. If the orange light is illuminated, follow the fill instructions in this manual to refill the tank. |
| | Start button not pressed. | Press and hold the Start button for 2 seconds to begin fogging. |
| | Not plugged in. | Check to make sure that the power cord is plugged into both the Fogger and a wall outlet. Then, check to see that the wall outlet is working. The green status indicator light should be illuminated when properly set up. |
| Green indicator light is blinking | Reservoir Door is not closed correctly. | Close Reservoir Door making sure it "clicks" when closed. |
| | Magnet in Reservoir Door is not in place. | Call Sanosil Customer Service. |
| No power | The power cord is not plugged in or the power source is not on. | Check to make sure that the power cord is plugged into both the Fogger and the wall outlet. Then, check to see that the outlet is working. The green status indicator light should be illuminated when properly set up. |
| Knocking noise | The compressor is not running properly. | Call Sanosil Customer Service. |

Disinfecting procedure is interrupted

Power loss during treatment process or other unforeseen circumstances.

Confirm power has been restored. Re-enter room one hour after hydrogen peroxide concentration level is determined to be at or below 1 ppm and ventilation process has been completed. Restart treatment process from beginning.

11. Replacement Parts

To order replacement parts, contact Sanosil Customer Service at 1 877 726 6745, Monday through Friday, 9:00AM to 5:00PM EST. For International calls dial +1 302 454 8102.

| Part | Part Number |
|-------------------------------------|---------------|
| 110V Power Cord (8') | 0750-110VPC |
| 220V Power Cord (8') | 0750-220VPC |
| International 220V Plug Adapter Kit | 0750-220VADPK |
| Nozzle (includes nozzle and bolt) | 0750-000 |

12. Re-Order Number

| Part | Part Number |
|---|--------------|
| 110V Sanosil Halo Fogger (US and Canada) | 0750-110 |
| 220V Sanosil Halo Fogger | 0750-220 |
| Sanosil HALOMIST | |
| Case of four 1-Gallon (3.8L) Refill Bottles | S010N0G4 |
| Sanosil Power Module | 20PMOD12-110 |
| CI – H202 Test Strips | H202STPS-50 |

13. Storage and Disposal

Sanosil Halo Fogger

Storage: Store in a safe, dry location. Do not place anything on top of the device. Store in an upright position. Keep the refill door closed.

Do not allow Sanosil HALOMIST to be stored in the Sanosil Halo Fogger for longer than one year.

Disposal: Electrical and electronic devices may not be disposed of with domestic waste. This product is in accordance with the law “waste electrical and electronic equipment” (WEEE).

Please contact your local representative for more information.

14. Specifications for Sanosil Halo Fogger

Mechanical

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| | |
|--------|--------------------------------|
| Height | 40.0" (101.5 cm) |
| Width | 13.25" (33.5 cm) |
| Depth | 18.5" (47 cm) |
| Weight | Approximately 50 lbs (22.5 kg) |

Electrical

| | |
|--------------------|---|
| Power Requirements | North American Version: 110V International Version: 220V |
| Certification | MET UL 969, MET CE |
| Current Rating | 4 amps |
| Fuse | 10 amps, 250 volt, slow acting, 5 x 20mm |
| Electrical Rating | 4 amps, 115 volt, 60 Hz (220 volt, 50 Hz for the 220V Fogger) |

Performance

| | |
|-----------------|-----------------------------|
| Nozzle Flow | 1.0 oz / min +/- 20% |
| Volumes treated | 400 – 3,660 ft ³ |